

In the Claims:

1-4 (Cancelled)

5. (Previously Presented) A device for managing respiration of a patient comprising:

at least one electrode configured to be coupled to tissue of a patient's body wherein the at least one electrode is configured to deliver electrical stimulation to the tissue to thereby elicit a diaphragm respiratory response;

a sensor configured to sense information corresponding to the patient's respiration;  
and

a responsive device coupled to the at least one electrode, the responsive device being configured to respond to information sensed by the sensor by controlling electrical stimulation delivered to the tissue through the at least one electrode

wherein the sensor is configured to sense and the responsive device is configured to respond to information corresponding to a patient's inspiration rate.

6. (Previously Presented) A device for managing respiration of a patient comprising:

at least one electrode configured to be coupled to tissue of a patient's body wherein the at least one electrode is configured to deliver electrical stimulation to the tissue to thereby elicit a diaphragm respiratory response;

a sensor configured to sense information corresponding to the patient's respiration;  
and

a responsive device coupled to the at least one electrode, the responsive device being configured to respond to information sensed by the sensor by controlling electrical stimulation delivered to the tissue through the at least one electrode;

wherein the sensor is configured to sense and the responsive device is configured to respond to information corresponding to a patient's exhalation rate.

7-52. (Cancelled).

53. (Previously Presented) A device for managing respiration of a patient comprising:

at least one electrode configured to be coupled to tissue of a patient's body wherein the at least one electrode is configured to deliver electrical stimulation to the tissue to thereby elicit a diaphragm respiratory response;

a sensor configured to sense information corresponding to the patient's respiration, wherein said sensor is configured to sense respiratory response; and

a programming device configured to adjust stimulation parameters to elicit a desired respiratory response;

wherein said electrical stimulation comprises a burst of pulses and wherein the programming device is configured to adjust frequency of the pulses.

54. (Previously Presented) A device for managing respiration of a patient comprising:

at least one electrode configured to be coupled to tissue of a patient's body wherein the at least one electrode is configured to deliver electrical stimulation to the tissue to thereby elicit a diaphragm respiratory response;

a sensor configured to sense information corresponding to the patient's respiration, wherein said sensor is configured to sense respiratory response; and

a programming device configured to adjust stimulation parameters to elicit a desired respiratory response;

wherein said electrical stimulation comprises a burst of pulses and wherein the programming device is configured to adjust pulse width of the pulses.

55. (Previously Presented) A device for managing respiration of a patient comprising:

at least one electrode configured to be coupled to tissue of a patient's body wherein the at least one electrode is configured to deliver electrical stimulation to the tissue to thereby elicit a diaphragm respiratory response;

a sensor configured to sense information corresponding to the patient's respiration, wherein said sensor is configured to sense respiratory response; and

a programming device configured to adjust stimulation parameters to elicit a desired respiratory response;

wherein said electrical stimulation comprises a burst of pulses and wherein the programming device is configured to adjust duration of the pulses.

56. (Previously Presented) A device for managing respiration of a patient comprising:

at least one electrode configured to be coupled to tissue of a patient's body wherein the at least one electrode is configured to deliver electrical stimulation to the tissue to thereby elicit a diaphragm respiratory response;

a sensor configured to sense information corresponding to the patient's respiration, wherein said sensor is configured to sense respiratory response; and

a programming device configured to adjust stimulation parameters to elicit a desired respiratory response;

wherein the programming device is configured to adjust stimulation to control tidal volume of a respiratory cycle.

57. (Previously Presented) A device for managing respiration of a patient comprising:

at least one electrode configured to be coupled to tissue of a patient's body wherein the at least one electrode is configured to deliver electrical stimulation to the tissue to thereby elicit a diaphragm respiratory response;

a sensor configured to sense information corresponding to the patient's respiration, wherein said sensor is configured to sense respiratory response; and

a programming device configured to adjust stimulation parameters to elicit a desired respiratory response;

wherein the programming device is configured to adjust stimulation to control inspiration rate.

58. (Previously Presented) A device for managing respiration of a patient comprising:

at least one electrode configured to be coupled to tissue of a patient's body wherein the at least one electrode is configured to deliver electrical stimulation to the tissue to thereby elicit a diaphragm respiratory response;

a sensor configured to sense information corresponding to the patient's respiration, wherein said sensor is configured to sense respiratory response; and

a programming device configured to adjust stimulation parameters to elicit a desired respiratory response;

wherein the programming device is configured to adjust stimulation to control exhalation rate.

59-70 (Cancelled)

71. (Currently Amended) A method of controlling the respiration of a patient comprising the steps of:

sensing information corresponding to a characteristic of a patient's respiration in a first breath; comparing the characteristic to a desired characteristic; and

electrically stimulating tissue of a patient to elicit a diaphragm response to alter the patient's respiration in a second breath to cause the characteristic to approach the desired characteristic.

72. (Original) The method of claim 71 wherein the characteristic comprises respiration rate.

73 . (Original) The method of claim 71 wherein the characteristic comprises inspiration rate.

74. (Original) The method of claim 71 wherein the characteristic comprises exhalation rate.

75-93 (Cancelled)

94. (Previously Presented) A method for managing respiration of a patient comprising the steps of:

providing at least one electrode and coupling the at least one electrode to tissue of a patient's body whereby electrical stimulation to the tissue elicits a diaphragm respiratory response;

provide stimulation to the tissue;  
sensing respiratory response to adjust parameters of the stimulation to elicit a desired respiratory response;  
wherein the stimulation comprises a burst of pulses and further comprising the step of adjust frequency of the pulses to elicit the desired response.

95. (Previously Presented) A method for managing respiration of a patient comprising the steps of:

providing at least one electrode and coupling the at least one electrode to tissue of a patient's body whereby electrical stimulation to the tissue elicits a diaphragm respiratory response;  
provide stimulation to the tissue;  
sensing respiratory response to adjust parameters of the stimulation to elicit a desired respiratory response;  
wherein the stimulation comprises a burst of pulses and further comprising the step of adjust pulse width of the pulses to elicit the desired response.

96. (Previously Presented) A method for managing respiration of a patient comprising the steps of:

providing at least one electrode and coupling the at least one electrode to tissue of a patient's body whereby electrical stimulation to the tissue elicits a diaphragm respiratory response;  
provide stimulation to the tissue;  
sensing respiratory response to adjust parameters of the stimulation to elicit a desired respiratory response;  
wherein the stimulation comprises a burst of pulses and further comprising the step of adjusting duration of the pulses to elicit the desired result.

97. (Previously Presented) A method for managing respiration of a patient comprising the steps of:

providing at least one electrode and coupling the at least one electrode to tissue of a patient's body whereby electrical stimulation to the tissue elicits a diaphragm respiratory response;

provide stimulation to the tissue;

sensing respiratory response to adjust parameters of the stimulation to elicit a desired respiratory response; and

adjusting stimulation to control tidal volume of a respiratory cycle.

98. (Previously Presented) A method for managing respiration of a patient comprising the steps of:

providing at least one electrode and coupling the at least one electrode to tissue of a patient's body whereby electrical stimulation to the tissue elicits a diaphragm respiratory response;

provide stimulation to the tissue;

sensing respiratory response to adjust parameters of the stimulation to elicit a desired respiratory response; and

adjusting stimulation to control inspiration rate.

99. (Previously Presented). A method for managing respiration of a patient comprising the steps of:

providing at least one electrode and coupling the at least one electrode to tissue of a patient's body whereby electrical stimulation to the tissue elicits a diaphragm respiratory response;

provide stimulation to the tissue;

sensing respiratory response to adjust parameters of the stimulation to elicit a desired respiratory response; and

adjusting stimulation to control exhalation rate.

100. (Currently Amended) A device for managing respiration of a patient comprising:

at least one electrode configured to be coupled to tissue of a patient's body;

a sensor configured to sense information corresponding to the respiration waveform of a patient's respiration;

a stimulation pulse generator configured to deliver electrical stimulation to the tissue through the at least one electrode to thereby elicit a diaphragm respiratory response comprising a respiration waveform having an inspiration portion and an exhalation portion; and

a responsive device coupled to the stimulation pulse generator, the responsive device being configured to respond to information sensed by the sensor by controlling electrical stimulation delivered to the tissue through the at least one electrode to control a parameter of a respiration waveform of a subsequent respiration cycle.

~~wherein the stimulation pulse generator is configured to control at least one of said inspiration portion and expiration portion of the respiration waveform.~~

101. (Previously Presented) The device of claim 100 wherein the pulse generator is configured to control the rate of inspiration.

102. (Previously Presented) The device of claim 100 wherein the pulse generator is configured to control the rate of exhalation.

103- 105 (Cancelled)

106. (Previously Presented) The device of claim 100 wherein the stimulation pulse generator is configured to manipulate the respiration waveform to control the partial pressure of carbon dioxide of the patient's blood.

107 (Previously Presented) The device of claim 100 wherein the stimulation pulse generator is configured to manipulate the respiration waveform to control the level of oxygen in the patient's blood.

108. (Previously Presented) The device of claim 100 wherein the stimulation pulse generator is configured to manipulate the inspiration time.

109. (Previously Presented) The device of claim 100 wherein the stimulation pulse generator is configured to manipulate the inspiration amplitude.

110. (Previously Presented) The device of claim 100 wherein the stimulation pulse generator is configured to manipulate the exhalation time.

111. (Previously Presented) The device of claim 100 wherein the stimulation pulse generator is configured to manipulate the exhalation amplitude.

112. (Previously Presented) The device of claim 100 further comprising an apnea detector coupled to the sensor and configured to detect an apnea event.

113. (Previously Presented) A device for managing respiration of a patient comprising:  
at least one electrode configured to be coupled to tissue of a patient's body; and  
a stimulation pulse generator configured to deliver electrical stimulation to the tissue through the at least one electrode to thereby elicit a diaphragm respiratory response;  
a sensor configured to sense information corresponding to the patient's respiration;  
and

a responsive device coupled to the at least one electrode, the responsive device being configured to respond to information sensed by the sensor by controlling electrical stimulation delivered to the tissue through the at least one electrode to adjust stimulation delivered through the at least one electrode based upon information sensed by the sensor, to elicit a respiratory response substantially similar to a predetermined respiratory waveform.

114. (Previously Presented) The device of claim 113 wherein the predetermined respiratory waveform comprises an intrinsic respiratory waveform for the patient.



115. (Previously Presented) The device of claim 5 wherein the responsive device is configured to adjust stimulation delivered to said at least one electrode to manipulate inspiration rate.

116. (Previously Presented) The device of claim 115 wherein the responsive device is configured to adjust stimulation delivered to said at least one electrode to manipulate inspiration duration.

117. (Previously Presented) The device of claim 116 wherein the responsive device is configured to induce a slower inspiration rate with respect to an intrinsic inspiration rate and a longer inspiration duration with respect to an intrinsic inspiration duration.

118. (Previously Presented) The device of claim 5 wherein the responsive device is configured to manipulate an inspiration waveform of an inspiration cycle to manipulate blood PCO<sub>2</sub>.

119. (Previously Presented) The device of claim 5 wherein the responsive device is configured to manipulate the respiration waveform to control the level of oxygen in the patient's blood.

120. (Previously Presented) The device of claim 6 wherein the responsive device is configured to adjust stimulation delivered to said at least one electrode to manipulate exhalation rate.

121. (Previously Presented) A method of treating a patient comprising: controlling partial pressure of carbon dioxide of blood of a patient by:

providing at least one electrode coupled to tissue of a patient's body; and a stimulation pulse generator configured to deliver electrical stimulation to the tissue through the at least one electrode;

eliciting a diaphragm respiratory response comprising a respiration waveform having an inspiration portion and an exhalation portion;

controlling at least one of said inspiration portion and expiration portion of the respiration waveform.

122. (Previously Presented) The method of claim 121 wherein the method of treating the patient comprises treating sleep apnea.

123. (New) A device for managing respiration of a patient comprising:

at least one electrode configured to be coupled to tissue of patient's body wherein the at least one electrode is configured to deliver electrical stimulation to the tissue to thereby elicit a diaphragm response; and

a stimulator configured to deliver a stimulation signal to the tissue through the at least one electrode to elicit an inspiration duration different from an intrinsic inspiration duration of an intrinsic breath.

124. (New) The device of claim 123 wherein the stimulator is configured to deliver a stimulation signal to the tissue through the at least one electrode to elicit an increased inspiration duration with respect to an intrinsic inspiration duration of an intrinsic breath.

125. (New) The device of claim 123 wherein the stimulator is configured to deliver a stimulation signal to the tissue through the at least one electrode to elicit a decreased exhalation duration with respect to an intrinsic exhalation duration of an intrinsic breath.

126. (New) A device for managing respiration of a patient comprising:

at least one electrode configured to be coupled to tissue of patient's body wherein the at least one electrode is configured to deliver electrical stimulation to the tissue to thereby elicit a diaphragm response; and

a stimulator configured to deliver a stimulation signal to the tissue through the at least one electrode to elicit an exhalation duration different from an intrinsic exhalation duration of an intrinsic breath.

127. (New) The device of claim 123 wherein the stimulator is configured to deliver a stimulation signal to the tissue through the at least one electrode to elicit a decreased exhalation duration with respect to an intrinsic exhalation duration of an intrinsic breath.

128. (New). A device for managing respiration of a patient comprising:

at least one electrode configured to be coupled to tissue of a patient's body wherein the at least one electrode is configured to deliver electrical stimulation to the tissue to thereby elicit a diaphragm response;

a sensor configured to sense information corresponding to the patient's respiration;  
and

a parameter adjuster configured to adjust at least one stimulation parameter based at least in part on information sensed by the sensor to elicit a desired diaphragm response;

wherein the parameter adjuster is configured to adjust stimulation to elicit a diaphragm response to control inspiration duration of a respiratory cycle.

129. (New) The device of claim 128 wherein the parameter adjuster is configured to adjust at least one stimulation parameter to induce a longer inspiration duration with respect to an intrinsic inspiration duration.

130. (New) The device of claim 128 wherein the parameter adjuster is configured to adjust at least one stimulation parameter to control an exhalation duration.

131. (New) The device of claim 129 wherein the parameter adjuster is configured to adjust at least one stimulation parameter to induce a shorter exhalation duration with respect to an intrinsic exhalation duration.

132. (New) A method for managing respiration of a patient comprising the steps of:  
providing at least one electrode and coupling the at least one electrode to tissue of a patient's body whereby electrical stimulation to the tissue elicits a diaphragm response;  
providing stimulation to the tissue; and  
sensing a diaphragm response and adjusting parameters of the stimulation to control inspiration duration of a respiratory cycle with respect to a baseline inspiration duration.
133. (New) The method of claim 132 wherein the step of sensing a diaphragm response and adjusting the parameters of stimulation comprises adjusting the parameters of stimulation to control exhalation duration of a respiratory cycle with respect to a baseline exhalation duration.
134. (New) The method of claim 71 wherein the characteristic comprises an inspiration duration.
135. (New) The method of claim 134 wherein the desired characteristic comprises an increased inspiration duration with respect to an intrinsic inspiration duration.
136. (New) The method of claim 71 wherein the characteristic comprises an exhalation duration.
137. (New) The method of claim 136 wherein the desired characteristic comprises a shorter exhalation duration with respect to an intrinsic exhalation duration.
138. (New) The method of claim 71 wherein the step of sensing information in the first breath comprises sensing intrinsic information.
139. (New) The device of claim 108 wherein the responsive device is configured to induce a longer inspiration duration with respect to an intrinsic inspiration duration.

140 (New) The device of claim 139 wherein the responsive device is configured to induce a shorter inspiration duration with respect to an intrinsic inspiration duration.

**Pending Claims**

Claims 5, 6, 53-58, 71-74, 94-122, are currently pending and presented for Examination in this application. New claims 123-140 to have been added and are presented for examination.

**Double Patenting**

In response to Examiner's provisional Double Patenting Rejection, Applicant would file a terminal disclaimer in this application to obviate the double patenting rejection if such terminal disclaimer were necessary to expeditiously move prosecution forward in this application.

**Claim Rejections – 35 USC § 103 – Testerman et al. and Christopherson et al.**

Claims 5-6, 53-55, 57-58, 71-74, 94-96 and 98-122 stand rejected under 35 U.S.C. 103(a) as being obvious over Testerman et al (US 5,522,862) in view of Christopherson et al (US 5,895,360) Examiner states:

Testerman et al. discloses the claimed invention except for the stimulation of the diaphragm. Christopherson et al teaches that it is known to "Preferably the muscle stimulated in an upper airway muscle such as the genioglossus muscle stimulated by a cuff electrode placed around the hypoglossal nerve. However, there may be other upper airway muscles or nerves which can be used for stimulation to perform the same function and also other nerves or muscles apart from the upper airway which may be stimulated, such as the diaphragm, to treat respiratory disorders, such as, for example, sleep apnea" as set forth in column 6, lines 30-37.

Examiner then concludes:

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the upper airway stimulation as taught by Testerman et al. with the diaphragm stimulation as taught by Christopherson et al., since such modification to the stimulation performs the same function and it is know to modify respiratory treatment to meet specific patient needs.